

be delineated. For arthrography, slowly inject 1.0 to 5 mL directly into the joint to be delineated. For discography, slowly inject 0.5 to 1.0 mL directly into the disc to be delineated. For sialography, slowly inject 0.5 to 1.0 mL into the duct to be delineated. For delineation of fistulous tracts, slowly inject quantity necessary to fill the tract. For delineation of peritoneal hernias, inject 0.5 to 1.0 mL per pound of body weight directly into the peritoneal cavity.

(2) *Indications for use.* For visualization in excretion urography, including renal angiography, uretography, cystography, and urethrography; aortography; angiocardiology, peripheral arteriography, and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography; and as an aid in delineating peritoneal hernias and fistulous tracts.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16186, Mar. 25, 2014]

#### § 522.650 Dihydrostreptomycin sulfate injection.

(a) *Specifications.* Each milliliter contains dihydrostreptomycin sulfate equivalent to 500 milligrams of dihydrostreptomycin.

(b) *Sponsors.* See Nos. 054771 and 055529 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.200 of this chapter.

(d) *Conditions of use—*(1) *Amount.* Administer 5 milligrams per pound of body weight by deep intramuscular injection every 12 hours, for 3 to 5 days or until the urine is free of leptospira for at least 72 hours as measured by darkfield microscopic examination.

(2) *Indications for use.* Treatment of leptospirosis in dogs and horses due to *Leptospira canicola*, *L. icterohemorrhagiae*, and *L. pomona*; in cattle due to *L. pomona*; and in swine due to *L. pomona*; and *L. grippotyphosa*.

(3) *Limitations.* Discontinue use 30 days before slaughter for food. Not for use in animals producing milk because use of the drug will contaminate the milk. Federal law restricts this drug to

use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 79 FR 16187, Mar. 25, 2014]

#### § 522.690 Dinoprost solution.

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to 5 milligrams (mg) dinoprost.

(b) *Sponsors.* See Nos. 054771 and 059130 in § 510.600(c) of this chapter.

(c) *Special considerations.* (1) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) *Conditions of use—*(1) *Horses—*(i) *Amount.* 1 mg per 100 pounds of body weight as a single intramuscular injection.

(ii) *Indications.* For its luteolytic effect to control timing of estrus in estrus cycling mares and in clinically anestrus mares that have a corpus luteum.

(iii) *Limitations.* Not for use in horses intended for food.

(2) *Cattle—*(i) *Beef cattle and nonlactating dairy heifers—*(A) *Amount.* 25 mg as an intramuscular injection either once or twice at a 10- to 12-day interval.

(B) *Indications.* For its luteolytic effect to control timing of estrus and ovulation in estrus cycling cattle that have a corpus luteum.

(ii) *Beef cattle and nonlactating dairy heifers—*(A) *Amount.* 25 mg as a single intramuscular injection.

(B) *Indications.* For treatment of pyometra (chronic endometritis).

(iii) *Nonlactating cattle—*(A) *Amount.* 25 mg as a single intramuscular injection during the first 100 days of gestation.

(B) *Indications.* For its abortifacient effect in nonlactating cattle.

(iv) *Lactating dairy cattle—*(A) *Amount.* 25 mg as a single intramuscular injection.

## § 522.723

(B) *Indications.* For treatment of unobserved (silent) estrus in lactating dairy cattle that have a corpus luteum.

(v) Dinoprost solution as provided by No. 000009 in § 510.600(c) of this chapter may be used concurrently with progesterone intravaginal inserts as in § 529.1940 of this chapter.

(3) *Swine*—(i) *Amount.* 10 mg as a single intramuscular injection.

(ii) *Indications.* For parturition induction in swine when injected within 3 days of normal predicted farrowing.

[67 FR 41824, June 20, 2002, as amended at 79 FR 16187, Mar. 25, 2014]

## § 522.723 Diprenorphine.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams of diprenorphine hydrochloride.

(b) *Sponsors.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(2) *Indications for use.* The drug is used for reversing the effects of etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(3) *Limitations.* For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

[79 FR 16187, Mar. 25, 2014]

## § 522.770 Doramectin.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams of doramectin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds).

## 21 CFR Ch. I (4–1–14 Edition)

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

(iii) *Limitations.* Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal.

(2) *Swine*—(i) *Amount.* 300 micrograms per kilogram (10 milligrams per 75 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.

(iii) *Limitations.* Administer as a single intramuscular injection. Do not slaughter swine within 24 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 53321, Oct. 11, 1996, as amended at 62 FR 44410, Aug. 21, 1997; 62 FR 62242, Nov. 21, 1997; 63 FR 68183, Dec. 10, 1998; 64 FR 13509, Mar. 19, 1999; 79 FR 16187, Mar. 25, 2014]

## § 522.775 Doxapram.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) doxapram hydrochloride.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For intravenous use in dogs and cats at a dose of 2½ to 5 mg per pound (lb) body weight in barbiturate anesthesia, 0.5 mg/lb in inhalation anesthesia; for intravenous use in horses at 0.25 mg/lb body weight in barbiturate anesthesia, 0.2 mg/lb in inhalation anesthesia, 0.25 mg/lb with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.